HHS Releases HTI-5 Proposed Rule

Digital Health 12.22.25

The U.S. Department of Health and Human Services (HHS), through the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC), has released the Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity (HTI-5) Proposed Rule . ASTP/ONC identifies three primary objectives in HTI-5, each aimed at streamlining compliance while strengthening data access and interoperability. These include (i) reducing burden in the Health IT Certification Program, (ii) revisiting the information blocking regulatory framework by proposing to revise or remove certain definitions, conditions, and exceptions that have been susceptible to misuse or overbroad interpretation, and (iii) reorienting the Certification Program around FHIR®-based application programming interfaces (APIs) and modern interoperability standards.

The HTI-5 Proposed Rule will be open for public comment for 60 days following publication in the Federal Register. ASTP/ONC has encouraged health IT developers, providers, digital health companies, and other stakeholders to review the proposal in full, given the breadth of changes contemplated. ASTP/ONC's press release and fact sheet about the proposed rule can be found here.

In tandem with HTI-5, ASTP/ONC is also withdrawing certain proposals not yet finalized from the HTI-2 proposed rule.

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